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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,283	03/13/2002	Susan B. Dillon	P50951	8717

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SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER
TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/088,283	Dillon et al
Examiner	**Art Unit**
R.S. Travers J.D., Ph.D.	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-25 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines neither those compounds possessing CBSP/p38 inhibitor activity useful for treating those viral diseases herein envisioned, nor a method for ascertaining compounds possessing this activity absent an individual assay of compounds. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of those compounds possessing CBSP/p38 inhibitor activity useful for treating those viral diseases herein envisioned examples are set forth, thereby failing to provide sufficient working examples. Additionally, a method for ascertaining compounds possessing this activity, absent an individual assay of compounds, is not recited in the instant specification. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all compounds possessing CBSP/p38 inhibitor activity useful for treating those viral diseases herein envisioned, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-13 and 18-22 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 14 and 23 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Those compounds critical, or essential, to the practice of the invention are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). It is well settled patent law that material essential for practicing the invention as claimed can only be incorporated by reference by citation of issued United States Patents. In the instant case Applicants have improperly attempted to employ publications other than issued U.S. patents to incorporate critical information by reference.

Claims 1-13, 18-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-13 and 18-22 are rendered indefinite by the phrase " compounds possessing CBSP/p38 inhibitor" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments that possess CBSP/p38 inhibitor activity are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term

fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Adams et al (644).

Claims, 18, 21, 23 and 25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Adams et al (644), in view of the Merck Manual.

Applicants' attention is directed to the Merck Manual (page 1000) teaching the general incapacitating nature of influenza, and those complications herein envisioned as collateral to this malady. In the instant application supra, the claims are directed treating a disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing this therapeutic utility provide relief for those effects collateral to this malady, as set forth in the Merck Manual. Well settled patent law charges the skilled artisan with the possession of that knowledge residing in texts on all subject matter recited in the instant claims. Thus,

possessing the knowledge, this skilled artisan would understand the nature of those diseases herein treated, including those dangers herein recited as collateral to the influenza therapy herein claimed.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-7, 10, 14-16, 18, 21, 23-25 are rejected under 35 U.S.C. § 103 as being unpatentable over Adams et al patents, in view of Merck Manual.

Adams et al teach the claimed compounds, and the penumbra of compounds encompassing those compounds, as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form ((048) pages 38 and 40, (644) column 12, lines 49-50, column 58, line 64, (499), column 28, lines 45-60, (992) column 1, line 54). These medicaments are taught as inhibitors of p38 and useful for treating

viral disease and inflammation, to include influenza, and those symptoms collateral to influenza. Claims 7, 18, 21, 23 and 25, and the primary reference, differ as to:

1) the recitation of symptomatology collateral to influenza infections, and

2) specific recitation of the compound recited in claims 15 and 24.

Applicants' attention is directed to the Merck Manual (page 1000) teaching the general dehabilitating nature of influenza, and those complications herein envisioned as collateral to this malady. In the instant application supra, the claims are directed treating a disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a therapeutic utility provide relief for those effects collateral to this malady, as set forth in the Merck Manual. Well settled patent law charges the skilled artisan with the possession of that knowledge residing in texts directed to that subject matter recited in the instant claims. Thus, this skilled artisan would understand the nature of the claimed disease therapy herein provided as including therapy for those dangers herein recited as collateral to the influenza therapy herein envisioned. Possessing these teachings the skilled artisan would have seen the employment of these compounds for treating influenza as obvious to the skilled artisan.

As stated above, Adams et al teach the claimed compounds, and the penumbra of compounds encompassing those compounds, as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These

medicaments are taught as useful for treating viral disease and inflammation, thus, encompassing influenza, and those symptoms collateral to influenza

Claims 8, 9, 11, 12, 13, 19, 20 and 22 are rejected under 35 U.S.C. § 103 as being unpatentable over Adams et al patents, in view of Merck Manual, as set forth above for claims 1-7, 10, 14-16, 18 21, 23-25, in further view of the Wilkowski et al patents.

The Wilkowski et al patents teach the claimed compounds, and the penumbra of compounds encompassing those compounds, as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating viral disease and inflammation, to include influenza, and those symptoms collateral to influenza. Claims 8, 9, 11, 12, 13, 19, 20 and 22, and the primary reference, differ as to:

1) the concomitant employment of these medicaments.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two conventional anti-influenza agents. It would follow that the recited claims

define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claim 17 is rejected under 35 U.S.C. § 103 as being unpatentable over Adams et al patents, in view of Merck Manual, as set forth above for claims 1-7, 10, 14-16, 18 21, 23-25, in further view of Bemis et al.

As stated above, Adams et al teach the claimed compounds, and the penumbra of compounds encompassing those compounds, as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form ((048) pages 38 and 40, (644) column 12, lines 49-50, column 58, line 64, (499), column 28, lines 45-60, (992) column 1, line 54). These medicaments are taught as inhibitors of p38 and useful for treating viral disease and inflammation, to include influenza, and those symptoms collateral to influenza. Claims 7, 18, 21, 23 and 25, and the Bemis et al reference, differ as to:

1) the recitation of a specific teaching of influenza infections therapy.

Applicants' attention is directed to Bemis et al teaching the compounds recited in claim 17 as possessing p38 inhibition activity, general antiviral activity and as effective in treating fever. In the instant application, the claims are directed treating a disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing this therapeutic utility provide relief for those effects collateral to this malady, as set forth in the Merck Manual. Well

settled patent law charges the skilled artisan with possessing that general knowledge residing in texts disclosing that subject matter recited in the instant claims. Thus, this skilled artisan would understand the nature of the disease herein treated to include those dangers herein recited, and see therapy for such symptoms as collateral to the influenza therapy herein envisioned. Thus, this skilled artisan would understand the nature of the disease herein treated included those dangers herein recited as collateral to general influenza therapy as herein envisioned. Possessing these teachings the skilled artisan would have seen the employment of the prior art compounds for treating influenza as obvious to the skilled artisan.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617